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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/646,898

Applicant(s)

OPHEIM, JOAR

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/12/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

The receipt is acknowledged of applicant's IDS, filed 01/12/04.

Claims 1-13 are pending and included in the prosecution.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,346,231; claims 1-7 of U.S. Patent No. 6,641,837; and claims 1-6 of U.S. Patent No. 6,652,879. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the claims in the issued patents and the present claims are directed to the same subject matter that is a flavored capsule encapsulating

Art Unit: 1615

a dose of fish oil and comprising gelatin or vegetable starch, from 10-35% of capsule softener selected from glycerol and sorbitol, from 6-10% water and flavor.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe the "quantity which improves the taste of the capsule". The specification describes on page 3, lines 16 and 17 that the flavor of the capsule improves the taste of the capsule and gelatin. The specification describes the function of the flavoring agent in the capsule is to improve the taste, and on page 6, lines 14-21 and on page 7, lines 1 and 2, discloses specific amounts that perform that function, which is 1%, and can be reduced to 0.25 to 0.5%. Therefore, the specification lacks support to the broad term "quantity that improves the taste", but described only specific amounts in the capsule shell and their criticality. Regarding claims 6 and 7, the claims recite the limitation "whereby the water-soluble flavoring promotes the ingestion of the fish oil dose". Although this limitation is a

functional limitation and does not impart patentability to the composition claims, but it lacks support in the specification.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,141,961 ('961) in combination with US 5,955,102 ('102).

US '961 teaches a soft gelatin shell encapsulating a dose of pharmaceutical composition which can be a nutritional supplements such as fatty acids. The shell of the gelatin capsule comprising gelatin, from about 10 to 35% of polyols such as glycerin (glycerol), from about 15 to 25% water, and flavoring. See the abstract; col.6, lines 25-26, 55-56; col.8, lines 1, 35-56; col.9, lines 1-3, 15-20, 25-33, 40-41, 49-55.

US '961 does not teach the claimed amount of the water, or fish oil as a dietary supplement.

Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule. The reference does not disclose if the amount of 15-25%

before drying or after drying. In any event, the amount of water does not impart patentability to the claims, absent evidence to the contrary.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gelatin capsule disclosed by US '961 that comprises gelatin, softener, water and flavor that used to deliver dietary supplement and replace the dietary supplement by the fish oil disclosed by US '102, motivated by the teaching of US '102 that the gelatin capsules are the preferred delivery method for the fish oil, with reasonable expectation of having a gelatin capsule comprising shell containing flavoring agent as disclosed by US '961 to deliver fish oil to the patient in need with great success.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

IG

*Isis Ghali*

**ISIS GHALI**  
**PATENT EXAMINER**